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510(k) Summary

JUN - 6 2011

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products, 33 Technology Drive
Irvine, CA 92618

Establishment Registration Number: 2084725

Contact Person
Nancy Chu
Manager, Regulatory Affairs
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Date: May 27, 2011

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Sterilization Wrap Sterilization Process Indicator
Common/Usual Name:	Sterilization Pouch / Roll with Chemical Indicator
Product Classification:	Class II
Proprietary Name:	Tyvek® Pouch/Roll with STERRAD® Chemical Indicator

2. PREDICATE DEVICES

STERRAD® Sterilization Pouch, which is currently manufactured and distributed by Advanced Sterilization Products [510(k) Notification K951295, cleared May 19, 1995].

STERRAD® Chemical Indicator Strip, which is currently manufactured and distributed by Advanced Sterilization Products [510(k) Notification K921910, cleared October 4, 1993].

3. INDICATIONS FOR USE

Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD® 100NX™ Sterilizer and to indicate, by color change that the pouch has been exposed to sterilant. After completion of the sterilization process, the pouch/roll maintains sterility until the seal of the pouch/roll is opened.

The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to yellow (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® Sterilization Systems.

4. DESCRIPTION OF DEVICE

The Tyvek® Pouch/Roll with STERRAD® Chemical Indicator is intended to be used to contain medical devices to be terminally sterilized in the STERRAD® Sterilization Systems. The medical devices are inserted into the pouch/roll, sealed, and then sterilized in the STERRAD® Sterilization System. After completion of the sterilization process, the pouch/roll maintains sterility of the enclosed medical devices until the seal is opened. The pouch/roll is printed with a chemical indicator bar that changes from red to yellow (or lighter) when exposed to hydrogen peroxide vapor during the sterilization process in the STERRAD® Sterilization Systems.

The proposed pouches are constructed from Tyvek®/plastic films, with the STERRAD® Chemical Indicator printed onto the Tyvek® film. The self-seal pouch permits sealing of the pouch without need of heat-sealing equipment, while the heat sealed pouches and rolls are heat sealed prior to processing in the STERRAD® Sterilization Systems.

The STERRAD® Chemical Indicator offers an additional way to verify processing in the sterilization cycle. The Chemical Indicator should be used in addition to, not in place of, the biological indicator. STERRAD® Chemical Indicators do not signify sterilization; they only indicate that the indicator has been exposed to the hydrogen peroxide. The color of the Chemical Indicator changes from red to yellow (or lighter) when exposed to hydrogen peroxide.

5. SUMMARY OF NONCLINICAL TESTS

Performance testing was conducted to show that the Tyvek® Pouch/Roll with STERRAD® Chemical Indicator maintains sterility until the seal of the pouch/roll is opened, after completion of the sterilization process, and that the STERRAD® Chemical Indicator changes from red to yellow (or lighter) when exposed to hydrogen peroxide.

Table 1: Pouch/Roll with Chemical Indicator Performance Tests

Study	Results
Sterilant Penetration	Passed
Package Integrity	Passed
Maintenance of Package Integrity	Passed
Material Compatibility	Passed
Chemical Indicator Functionality	Passed
End Point / Post Processing Color Stability	Passed
Shelf Life	Passed
Biocompatibility	Passed

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6. COMPARISON OF TECHNICAL CHARACTERISTICS

Table 2: Summary of Comparison between Proposed Device and Predicate Devices

Characteristics	Proposed Pouch/Roll with Chemical Indicator	Predicate Pouch (K951295)	Predicate Chemical Indicator (K921910)
Pouch Construction: Tyvek® and transparent film	Yes	Yes	N/A
Siliconized Tyvek®	No	Yes	N/A
User heat seal	Yes	Yes	N/A
User self-seal	Yes	No	N/A
Chemical Indicator (CI)	Yes	No	Yes
CI substrate	Tyvek®	N/A	Styrene
Chemical reaction	Hydrogen peroxide	N/A	Hydrogen peroxide
Distinct color change	Red to yellow	N/A	Red to yellow
Single use device	Yes	Yes	Yes
Shelf life	24 months	N/A	12 months

7. OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the Tyvek® Pouch/Roll with STERRAD® Chemical Indicator performs as intended as a sterilization packaging system of medical devices that are being terminally sterilized in STERRAD® Sterilization Systems. The Chemical Indicator performs as intended for differentiating processed from unprocessed packages in the STERRAD® Sterilization Systems. These studies also show that the proposed pouches have the same intended use and met the same criteria as the predicate devices and are substantially equivalent.

Tyvek® is a registered trademark of Du Pont.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 6 2011

Ms. Nancy Chu
Manager, Regulatory Affairs
Advanced Sterilization Products
33 Technology Drive
Irvine, California 92618

Re: K103210
Trade/Device Name: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: May 6, 2011
Received: May 9, 2011

Dear Ms. Chu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103210

Device Name: **Tyvek® Pouch/Roll with STERRAD® Chemical Indicator**

Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD® 100NX™ Sterilizer and to indicate, by color change, that the pouch has been exposed to sterilant. After completion of the sterilization process, the pouch/roll maintains sterility until the seal of the pouch/roll is opened.

The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to yellow (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® Sterilization Systems.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use √ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie-Williams

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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(Posted November 13, 2003)